EXHIBIT E

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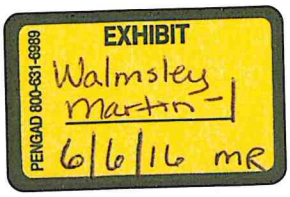

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Patricia J. Martin, et al. v. Ethicon, Inc.., et al No. 2:12-cv-00878	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Motley Rice Law Firm to give medical opinions related to Patricia J. Martin. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including the pubovaginal sling. I have

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attended training provided by Ethicon, Inc. regarding the TVT device. I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Patricia J. Martin:

- Siloam Springs Regional Hospital;
- Saint John Medical Center;
- Mercy Hospital Northwest Arkansas;
- International Urogynecology Associates;
- Mercy Medical Specialty;
- Northwest Arkansas Neurosurgery Clinic;
- Quick Care Clinic;
- Regional Medical Laboratory;
- Atlanta Urogynecology;
- LabCorp San Antonio;
- Northwest Arkansas;
- Regional Medical Laboratories
- Saint John Heart Institute
- Smith Drug;

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- TriCities Community;
- Ozark Foot and Ankle; and
- Saint John's Physicians;

In addition to the review of the medical records listed above, I performed an independent medical examination of Patricia J. Martin on April 26th, 2016. I have also reviewed the following medical literature and other TVM related documents and have relied, in part, on the documents below in addition to my medical and clinical experience in forming my opinions:

- AMA 8.08
- TVT Instructions for Use
- C.G. Nilsson et al "Seventeen years' follow-up of the tension free vaginal tape procedure for female stress urinary incontinence." Int. Urogynecol. J. (2013) 24:1265-69
- P. Hilton "A clinical and urodynamic study comparing the Stamey bladder neck suspension and suburethral sling procedures in treatment of genuine stress incontinence" British Journal of Obst. & Gynecol (February 1989, Vol 96, pp. 213-220
- H. Enzelsberger et. al "Comparison of Burch and Lyodura Sling Procedures for Repair of Unsuccessful Incontinence Surgery" Obstet & Gynecol, Vol 88, No. 2, August 1996
- A.S. Arunkalaivanan et al "Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire based study" Int. Urogynecol J (2003), 14: 17-23
- K. Guerrero et al "A randomized controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up" Int. Urogynecol J (2007) 18:1263-1270
- B. Welk et al, "Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontinence" JAMA Surgery, Published Online September 9, 2015.
- E. Petri et al., "Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS

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classification" Eur. J. of Obstet. & Gynecol. and Reprod. Bio. 165 (2010) 347-351

- B. Klosterhalfen et al., "Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair" Biomaterials (1998) 2235-46
- J. Anger et al., "Complications of Sling Surgery Among Female Medical Beneficiaries" Obstet. & Gynecol. Vol. 109, No. 3 (March 2007)
- P. Moalli et al, "Tensile Properties of five commonly used mid-urethral sling relative to the TVT" Int. Urogynecol J (2008) 19:655-663
- A. Clave et al, "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants" Int. Urogynecol J (2010) 21:261-270
- O. Chinthakanan et al., "Mesh Removal Following Sling/Mesh Placement: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-139-40
- O. Chinthakanan et al, "Indication and Surgical Treatment of MidUrethral Sling Complications: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-142-43
- E. Petri et al., "Comparison of late complications in retropubic and transobturator slings in stress urinary incontinence" Int. Urogynecol. J. (2012) 23:321-325
- S. Abbott et al., "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study" American J. of Obstet. & Gynecol (February 2014) 163.e1-8.
- G. Agnew et al, "Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral tape insertion for urinary stress incontinence" Int. Urogynecol J. (2014) 25:235-239
- J. Duckett et al, "Pain after suburethral sling insertion for urinary stress incontinence" Int. Urogynecol J. (2013) 24:195-201
- C. Skala et al., "The IUGA/ICS classification of complications of prosthesis and graft insertion" Int. Urogynecol J (2011) 22:1429-1435

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- K. Svabik et al., "Ultrasound appearances after mesh implantation – evidence of mesh contraction or folding?" Int. Urogynecol J. (2011) 22:529-533
- A. Rogowski et al., "Mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair" Int. Urogynecol. J. (2013) 24:2087-2092

Clinical History

- Sometime in 1995, Mrs. Martin underwent a hysterectomy for benign disease. She was placed on oral hormonal therapy (Cenestin) at that time.

- Sometime in 2003, Mrs. Martin developed dyspareunia. This was attributed to scarring from a prior episiotomy. She underwent a procedure to remove this scar tissue and her dyspareunia completely resolved.

- On June 4th, 2009, Mrs. Martin saw Dr. Chad Hill with complaints of stress urinary incontinence. She was found to have a grade 1 cystocele and rectocele, as well as urethral hypermobility, confirmed with a positive Q-tip test.

- On June 12th, 2009, Mrs. Martin underwent insertion of a TVT-O sling by Dr. Chad Hill. The procedure was uneventful. Dr. Hill memorializes using curved Mayo scissors as a spacer between the sling and the urethra to ensure tension-free placement. Cystoscopy was also performed and showed no bladder pathology or foreign bodies in the bladder.

- On April 16th, 2010, Mrs. Martin underwent posterior colporraphy by Dr. Hill to correct a symptomatic rectocele.

- On July 11th, 2011, she saw Dr. Hill with complaints of dyspareunia. Of note, she had been discontinued Cenestin due to a stroke. Her exam revealed a well healed colporraphy incision and

What did she relate it to?

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describe tenderness where ... ?

adequate introital caliber. She was prescribed Vagifem and topical Progesterone cream.

- On September 29, 2011, Mrs. Martin returned to Dr. Hill with complaints of severe anterior vaginal dyspareunia that has been present since her TVT-O and posterior colporraphy. She was referred to Dr. Spyridon Marinis for further management.

- On October 26th, 2011, Mrs. Martin saw Dr. Marinis with complaints of entry anterior vaginal wall dyspareunia that started after TVT tape insertion. There were also complaints of defecatory dysfunction after her posterior repair requiring splinting to completely defecate. Additionally, she had voiding complaints of urinary urgency with occasional urgency urinary incontinence, subjective feelings of incomplete bladder emptying, and slow stream. On exam, she was noted to have no visible erosion, but pain to palpation at the left vaginal sulcus which reproduced her dyspareunia pain. She also had reproducible pain to palpation of the obturator internus muscle. She was diagnosed with mononeuritis with genital neuropathy, dyspareunia, and nonspecific complications relating to her TVT-O sling. Dr. Marinis memorialized that she had bilateral pudendal neuropathy that could very well have been triggered by local irritation related to the TVT-O mesh. The patient desired removal of the left arm of the TVT-O tape.

- On December 22nd, 2011, Dr. Marinis performed surgery during which time he removed the segment of TVT-O tape from the right obturator foramen to the left obturator foramen. He noted that on the right side, the tape was more tense than that on the left side and was almost ready to erode through the vaginal epithelium being covered only by a transparent layer of tissue. He also performed cystoscopy which demonstrated moderated trabeculations. The pathological specimens submitted identified partially detached squamous mucosa with underlying fibrous tissue containing linear

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fragments of foreign material provoking a foreign body giant cell reaction.

- On March 8th, 2012, Mrs. Martin saw Dr. Roger Miklos with complaints of pelvic/bladder pain, dyspareunia, and voiding dysfunction. Her patient assessment questionnaire memorializes painful intercourse occurring always, usually leading to her avoiding sexual intercourse, with continuous bladder/pelvic pain. She complained of mixed urinary incontinence resulting in significant quality of life impairment, specifically her ability to do household chores, physical recreation, participation in social activities outside the home, as well as having continuous negative impact on her emotional health and feelings of frustration. Dr. Miklos documented that she had attempted intercourse after Dr. Marinis' surgery but still had pain. She felt that sling removal did not help her pain and that she can't allow her husband's penis to penetrate because the pain is too severe. Her pain was strictly at the vaginal opening, that she had no vulvar pain, and that she had pain with intercourse at entry. She was counseled towards vaginal and vulvar scar revision with perineoplasty and laparoscopic Burch procedure.

Methodology

My general opinions based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

Opinion No. 1

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Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2009 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- Recurrence of incontinence
- Bleeding, including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.

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• PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS

• Seroma
• Urge incontinence
• Urinary frequency
• Urinary retention
• Adhesion formation
• Atypical vaginal discharge
• Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina and peri-vaginal tissues persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

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The TVT IFU does not mention: mesh contraction; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event, nor does it mention the severity of the dyspareunia and the difficulty treating mesh-induced dyspareunia These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. These events were reported in the mid-urethral sling literature prior to when Mrs. Martin was implanted. In my opinion, a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

Opinion No. 2

Safer alternatives designs and procedures existed in 2009 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.

In 2009, alternative successful and safer sling alternatives were available including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Mrs. Martin was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh in the area of the pelvis and vagina. As such, Dr. Hill was not able to warn Mrs. Martin of the subsequent complications she has suffered from.

Opinion No. 3

Mrs. Martin suffered vaginal sling contraction and scar plate formation as a result of the physical properties of the TVT device. These conditions are documented in the medical records.

A. Contraction/Shrinkage

Mrs. Martin's TVT contracted post implantation. Dr. Marinis documented such during his surgical removal of part of the TVT-O tape documenting that "on the right side, the tape was more tense than that on the left side and was almost ready to erode through the vaginal epithelium being covered only by a transparent layer of tissue."

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I have observed "tense" pieces of transvaginal mesh in my clinical practice that is the result of post-implantation contraction or shrinkage of the mesh. Often times, when mesh sling contraction occurs, it can create an obstructed voiding pattern leading to symptoms of slow stream and urgency. When this process occurs, it can result in pathological changes to the bladder wall that manifest with bladder wall thickening and the development of trabeculations in the bladder, which histologically represent the deposition of type 4 collagen. Not only did Mrs. Martin complain of the above symptoms, but Dr. Marinis notes trabeculations during his cystoscopic evaluation of the bladder, findings not memorialized during Dr. Hill's 2009 cystoscopy.

B. Scar Plate

During the surgical removal of part of Mrs. Martin's sling, the excised sling was examined pathologically and found to contain partially detached squamous mucosa with underlying fibrous tissue containing linear fragments of foreign material provoking a foreign body giant cell reaction. This fibrous tissue, along with foreign body giant cell reaction, is consistent with the inflammatory response and subsequent deposition of fibrous tissue and scar that are proved by pelvic polypropylene mesh.

I have observed scar plate formation in patients such as Mrs. Martin who have had TVT slings implanted and removed.

Opinion No. 4

Mrs. Martin's vaginal pain and dyspareunia were caused by contraction of the TVT device, scar plate formation, and neuromuscular injury. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

I am able to rule in contraction, scarring, and neuromuscular injury as potential causes of Mrs. Martin's vaginal pain and dyspareunia. These conditions are documented in the medical records of Dr. Marinis and Dr. Miklos as previously stated above.

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Pain produced upon palpation of the left vaginal sulcus following sling insertion and persisting after sling removal enables me to rule in contraction and scarring as potential causes of Mrs. Martin's dyspareunia.

I am able to exclude paraurethral banding as a cause of Mrs. Martin's dyspareunia and vaginal pain because I have seen no paraurethral banding documented.

I am able to exclude vestibulitis, and lichen sclerosis as causes of Mrs. Martin's vaginal pain and dyspareunia as there is no evidence in the medical records of the presence of either of these conditions.

Neuromuscular injury is able to be ruled out as a potential cause of Mrs. Martin's dyspareunia. Although Dr. Marinis diagnosed bilateral pudendal neuropathy ("that could very well have been triggered by local irritation related to the TVT-O mesh") during his initial consultation with Mrs. Martin, Dr. Miklos' subsequent consultation and physical exam did not confirm this finding. During my independent medical exam of Mrs. Martin, I did not identify either pudendal neuropathy or evidence of any other pelvic neuromuscular injury.

Vaginal tissue atrophy is excludable as the cause of Mrs. Martin's dyspareunia as she never was diagnosed with this condition. Moreover, she was on estrogen replacement prior to and for a period of time subsequent to her sling surgery. Neither Dr. Marinis nor Dr. Miklos identify vaginal tissue atrophy during their evaluations of Mrs. Martin. During my independent medical exam of Mrs. Martin, I did identify mild atrophic vaginitis. The time course and location of Mrs. Martin's dyspareunia, however, are inconsistent with this condition therefore excluding it as a significant causal factor.

I am able to exclude pelvic floor dysfunction as the cause of Mrs. Martin's dyspareunia. Once again, although Dr. Marinis did entertain the diagnosis of pudendal neuropathy caused indirectly by the TVT-O mesh, he absence of documented tenderness to the pelvic floor musculature on multiple subsequent evaluations (including Dr. Miklos and myself) enables me to reasonably exclude pelvic floor dysfunction as a potential cause of her dyspareunia.

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Opinion No. 5

Mrs. Martin continues to have dyspareunia and urinary incontinence presently. As part of my expert review and preparation of my opinion regarding Ms. Martin, I performed an independent medical exam of this patient on May 3rd, 2016. At that time, the patient reported several bothersome symptoms including voiding dysfunction and dyspareunia. Her voiding dysfunction consisted of urinary incontinence, primarily urgency urinary incontinence. She also described urgency and hesitancy. She was able to avoid pad use by voiding frequently. With regards to her pelvic pain she described a pain sensation within the vaginal canal that on physical exam was reproducible along the left vaginal sulcus, in the area where her sling was excised and partially removed. She complained of pelvic pain only with intercourse, last attempted at least three years ago. During my independent medical exam, she became tearful when relating the loss of this type of intimacy with her husband.

Relevant findings on physical exam include mild vulvar atrophy as well indurated tissue in the area of her sling along the left vaginal sulcus.

As part of the foreign body reaction to synthetic mesh the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elasticity and compliance of these tissues. As such, when patients present with complications from synthetic mesh slings, they tend to develop a combination of voiding dysfunction, sometimes manifest as obstructive in nature, in addition to urinary incontinence that is often both stress incontinence in combination with urgency urinary incontinence. This relates to a combination of factors, one being the development of non-compliant "pipestem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (1) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis.

Opinion No. 6

Ms. Martin's future prognosis as it relates to her dyspareunia, and voiding dysfunction is guarded. Because she has pelvic mesh still inside of her body as

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well as scar tissue from her mesh-related surgeries, she will continue to suffer from dyspareunia. Moreover, she has pelvic tenderness and residual scar tissue in the area where her mesh was removed. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is extensive, complicated, and almost exclusively performed in tertiary academic centers. I anticipate that if heroic surgery were performed to remove all of her mesh and the scar tissue related to her mesh implant that she would develop further scarring and fibrosis inherent to this procedure.

In as much an autologous fascial sling or other procedures (not involving synthetic mesh) for incontinence might be considered if her mesh were to be removed, these would be more complicated at the current time because of the fact that she still has scar tissue and residual mesh present. Autologous fascial slings placed in the setting of scar tissue, a likely finding should she have her sling removed, would have a lower success rate and a higher complication rate than if it were performed in the absence of scarring. For this reason, Mrs. Martin is not an ideal candidate for this type of surgery and is best treated with medical therapy in combination with lifestyle modifications and pelvic floor physiotherapy. Although these interventions should be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from.

With regards to her dyspareunia, her symptoms might be ameliorated with sling and/or scar tissue removal. Once again, this would be a heroic procedure performed in a tertiary academic center and would likely create further fibrosis and scarring which would more likely than not result in persistent dyspareunia. In summary, within a reasonable degree of medical certainty, the voiding dysfunction and dyspareunia will be a lifelong condition for this patient.

These represent my current opinions in this case. As any additional material becomes available, I reserve the right to modify or add to this opinion.

Sincerely,

Konstantin Walmsley, M.D.